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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,876

11/28/2006

Daniel Tod Smithey

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07/07/2010

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

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07/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,876	Applicant(s) SMITHEY ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-52 is/are pending in the application.
- 4a) Of the above claim(s) 49-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The examiner acknowledges receipt of response to election/restriction requirement filed 04/21/2010, IDS and preliminary amendment filed 6/28/06. Claims 27-52 are pending.

Election/Restrictions

2. Applicant's election of Group I, claims 27-48 in the reply filed on 4/21/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Therefore, claims 49-52 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/21/2010.

Priority

4. The examiner acknowledges that application as a 371 of PCT/IB04/04287 filed 12/20/2004, which claims benefit of US provisional application 60/533,836.

Response to Amendment

5. New claims 27 and 28 show markings to indicate amendment of the new claims. If this were amendment of claims 27 and 28, the proper status identifiers should have been currently amendment. Applicant is requested to use appropriate status identifiers in all future communications.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 28, 30, 35-37, 39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 28 and 30 recite “greater than about” and within the “greater than about” are two ranges, one that is “greater than” and another that is “about.”

9. Claims 35-37 recite “less than about” and within the “less than about” are two ranges, one that is “less than” and another that is “about.”

10. Claims 39 and 40 recite “at least about” and within the “at least about” are two ranges, one that is “at least” and another that is “about.”

11. It is suggested that ---at least---, or ---less than---, or ---greater than--- or ---about--- be used in the appropriate claims.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 27-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Infeld et al. (WO 02/089835).

14. Infeld discloses solid oral pharmaceutical dosage form of amorphous nelfinavir (abstract), which is in the form of powder or granules compressed into tablet (page 6, line 14; page 7, line 29; page 8, lines 14, 20-28). The dosage form comprising the nelfinavir, poloxamer and other excipients (see Examples IV and V) comprises greater than 50% of the particle by

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weight of the nelfinavir and poloxamer and this dosage form meets claims 27 and 28 since a glass transition temperature of at least 50 °C as recited in claim 27 is a characteristic property of the drug and log P value of a drug that is greater than 6.5 as recited in claim 28 being characteristic property of the drug. While “said drug being dispersed within said poloxamer ... at least a portion of said poloxamer” is a process of making the dosage form and does not distinguish the patentability of the product, the mixing the nelfinavir and poloxamer at a temperature where the poloxamer is a solution ensures homogenous dispersion of the drug in the poloxamer in Infeld so that the limitation, though a process of making the product, is met.

15. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps and “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

16. Claims 29-37 and 42-44 recite the properties of the dosage form and as such the dosage of Infeld anticipated the dosage of claims 27 and 28 and as such dosage of Infeld meets claims 29-37 and 42-44.

17. The %amount of nelfinavir in the dosage of examples IV and V is at least 50% of the particles and at least 50% meets the limitations in claims 39-41.

18. Infeld teaches that the nelfinavir is amorphous and as such claim 38 is met.

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Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 27-30 and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Infeld et al. (WO 02/089835) in view of Beyerinck et al. (US 6,763,607).

22. Infeld has been described above to anticipate claims 27 and 28 and also claims 29 and 30. One of the goals of Infeld is to make enhance the bioavailability and dissolution of nelfinavir (page 3, lines 16, 17; page 4, lines 25, 26).

23. The composition of Infeld does not contain concentration enhancing polymers as recited in claims 45 and 46. But it is known in the art that enhancing the concentration of poorly soluble drug also enhances the bioavailability of the poorly soluble drugs. For example, Beyerinck discloses enhancing the concentration and bioavailability of a number of drugs, the work of Beyerinck is not limited to any specific drug except to the list of drugs disclosed in

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column 9, line 9 to column 11, line 19 and amongst this list is antivirals with acyclovir, nelfinavir and virazole named antivirals (column 9, lines 11, 19, 20; column 10, line 16; column 11, lines 44, 45; column 12, lines 16-18; column 18, lines 61-64; column 19, lines 7, 17-19, 52-57; column 21, lines 54-59). Beyerinck also teaches that blends of polymers such as the enteric polymers and the copolymers of polyoxyethylenes and polyoxypropylenes, which are the poloxamers can be used in enhancing the concentration and bioavailability of poorly soluble drugs (see column 13, line 49, column 17, lines 16-45 and claim 20).

24. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to enhance the bioavailability of the antiviral agent nelfinavir by using poloxamer. One having ordinary skill in the art would have been motivated to enhance the bioavailability and concentration of antivirals such as nelfinavir by using the teaching of Beyerinck where a blend of enteric polymers such as hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate and poloxamer are used with the expectation of further enhancing the concentration and bioavailability of nelfinavir.

25. Claims 47 and 48 recite the characteristic of the dosage form. Claims 45 and 46 are shown above as being obvious over Infeld in view of Beyerinck. Therefore, claims 47 and 48 being dependent on claim 45 and reciting the properties of the dosage form are also obvious over Infeld in combination with Beyerinck.

26. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618